

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

Track Three Cases

Case No. 17-md-2804

Judge Dan Aaron Polster

**PLAINTIFFS' OPPOSITION TO CERTAIN DEFENDANTS'
DAUBERT MOTION TO EXCLUDE THE OPINIONS
OFFERED BY JAMES RAFALSKI**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	2
III.	LEGAL STANDARDS REGARDING <i>DAUBERT</i> MOTIONS	3
A.	<i>Daubert</i> and Fed. R. Evid. 702	3
B.	The <i>Daubert</i> Inquiry Is Not Intended to Replace the Adversary System	5
C.	The <i>Daubert</i> Inquiry Is Focused on the Expert’s Methodology, Not on His or Her Conclusions	6
D.	Statistical Analysis Is an Appropriate Form of Expert Opinion.....	8
IV.	ARGUMENT	8
A.	Rafalski’s Opinions in Track Three are Consistent with the Court’s Holdings from Track One.....	8
B.	Rafalski’s Opinions Regarding Moving Defendants’ SOM Systems in Track Three Are Reliable	10
1.	Under controlling law, Mr. Rafalski may base his opinions on his professional experience without replicating a DEA investigation.	10
2.	Moving Defendants’ arguments against Rafalski’s conclusions go to weight, not admissibility.....	12
C.	Mr. Rafalski’s Opinions as to the Methodologies Used for Flagging Orders and Causation Are Reliable	15
V.	CONCLUSION	19

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Best v. Lowe’s Home Centers, Inc.</i> , 563 F.3d 171 (6th Cir. 2009)	5, 6, 7
<i>Brainard v. Am. Skandia Life Assur. Corp.</i> , 432 F.3d 655 (6th Cir. 2005)	4
<i>Burgett v. Troy-Bilt LLC</i> , 579 F. App’x 372 (6th Cir. 2014)	5
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993)	passim
<i>Decker v. GE Healthcare Inc.</i> , 770 F.3d 378 (6th Cir. 2014)	6
<i>In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.</i> , 348 F. Supp. 3d 698 (S.D. Ohio 2016)	6
<i>First Tennessee Bank Nat. Ass’n v. Barreto</i> , 268 F.3d 319 (6th Cir. 2001)	5
<i>Johnson v. Manitowoc Boom Trucks, Inc.</i> , 484 F.3d 426 (6th Cir. 2007)	10, 11
<i>Kipps v. Caillier</i> , 197 F.3d 765 (5th Cir. 1999)	4
<i>Kumho Tire Co., Ltd. v. Carmichael</i> , 526 U.S. 137 (1999)	passim
<i>Laski v. Bellwood</i> , 132 F.3d 33 (6th Cir. 1997)	5
<i>Masters Pharmaceutical, Inc. v. Drug Enforcement Administration</i> , 861 F.3d 206 (D.C. Cir. 2017)	2, 3, 15
<i>Masters v. City of Indep., Missouri</i> , 998 F.3d 827 (8th Cir. 2021)	6
<i>In re Nat’l Prescr. Opiate Litig.</i> , 2019 WL 3934490 (N.D. Ohio Aug. 20, 2019)	15, 16
<i>In re Nat’l Prescription Opiate Litig.</i> , No. 1:17-MD-2804, 2019 WL 3934597 (N.D. Ohio Aug. 20, 2019)	12

<i>Nelson v. Tennessee Gas Pipeline Co.,</i> 243 F.3d 244 (6th Cir. 2001)	4, 18
<i>In re Neurontin Mktg., Sales Practs., and Prods. Liab. Litig.,</i> 712 F.3d 21 (1st Cir. 2013).....	8
<i>In re Paoli R.R. Yard PCB Litig.,</i> 35 F.3d 717 (3d Cir.1994)	7
<i>Pride v. BIC Corp.,</i> 218 F.3d 566 (6th Cir. 2000)	8
<i>In re Scrap Metal Antitrust Litig.,</i> 527 F.3d 517 (6th Cir. 2008)	4, 6, 7
<i>Superior Prod. P’ship v. Gordon Auto Body Parts Co.,</i> 784 F.3d 311 (6th Cir. 2015)	6
<i>Tamraz v. Lincoln Elec. Co.,</i> 620 F.3d 665 (6th Cir. 2010)	4
<i>U.S. ex rel. Tennessee Valley Auth. v. 1.72 Acres of Land In Tennessee,</i> 821 F.3d 742 (6th Cir. 2016)	6
<i>Tyson Foods, Inc. v. Bouaphakeo,</i> 136 S. Ct. 1036 (2016)	8
<i>U.S. v. 14.38 Acres of Land, More or Less Situated in Leflore County,</i> 80 F.3d 1074 (5th Cir. 1996)	5
<i>U.S. v. Demjanjuk,</i> 367 F.3d 623 (6th Cir. 2004)	6
<i>U.S. v. Kalymon,</i> 541 F.3d 624 (6th Cir. 2008)	4, 5
<i>Ullman v. Auto-Owners Mut. Ins. Co.,</i> 502 F. Supp. 2d 737 (S.D. Ohio 2007).....	4
<i>United States v. Bonds,</i> 12 F.3d 540 (6th Cir. 1993)	7
<i>United States v. L.E. Cooke Co.,</i> 991 F.2d 336 (6th Cir. 1993)	7
<i>United States v. Lang,</i> 717 F. App’x 523 (6th Cir. 2017)	5, 12

<i>Wood v. Wal-Mart Stores E., LP</i> , 576 F. App'x 470 (6th Cir. 2014)	11
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Other Authorities

Fed. R. Evid. 702	<i>passim</i>
Fed. R. Evid. 702(a)	8

I. INTRODUCTION

Three of the Pharmacy Defendants, Giant Eagle, Rite Aid, and Walmart (collectively, “Moving Defendants”), have moved to exclude the opinions of former DEA Diversion Investigator James Rafalski. *See* Doc. #3855-2 and #3855-4, Certain Defendants’ *Daubert* Motion to Exclude the Opinions Offered by James Rafalski and Memorandum in Support (“Defs’ Memo”). With certain limited exceptions, this Court has previously denied the motion of two other Pharmacy defendants and the Manufacturer and Distributor defendants in Track One to exclude similar opinions offered by Mr. Rafalski. This Court should adhere to its prior ruling and, once again, permit Mr. Rafalski to offer his expert opinions.

Moving Defendants argue that Mr. Rafalski’s opinions should be excluded for three reasons. None has merit. First, Moving Defendants contend that Mr. Rafalski’s expert report offers opinions that were excluded in Track One. This is not so. Rather, Mr. Rafalski’s opinions in Track Three are consistent with the Court’s Track One ruling, which held that Mr. Rafalski may opine on the key components of an effective suspicious order monitoring program and on whether Defendants’ programs adequately implemented such components. Moving Defendants next argue that Mr. Rafalski’s methodology in Track Three is unreliable because, they say, he did not replicate his prior practice as a Diversion Investigator. But Mr. Rafalski need not replicate the precise steps of the investigations he conducted as a DEA Diversion Investigator in order to evaluate Defendants’ documents and testimony in this case and offer his expert opinion based on his professional experience. Finally, Moving Defendants contend that the seven algorithms Mr. Rafalski identifies for flagging suspicious orders are unreliable and would not be helpful to the jury. But in making this argument, Moving Defendants mischaracterize Mr. Rafalski’s opinions regarding the seven methodologies and their relation to his opinion that Defendants’ SOM failures

contributed to the opioid crisis in Lake and Trumbull Counties. The Court should deny Moving Defendants' motion in its entirety.

II. BACKGROUND

James E. Rafalski is a former Drug Enforcement Agency ("DEA") Diversion Investigator with twenty-six years of law enforcement experience, including significant experience related to the distribution of controlled substances under the Controlled Substances Act ("CSA"). He is knowledgeable about the federal law and regulations governing the distribution of controlled substances, and has training and experience relating to suspicious order monitoring ("SOM") systems, reporting of suspicious orders, data analysis from ARCOS, and the due diligence required of distributors before shipping an order flagged as suspicious. Mr. Rafalski has participated in multiple major investigations and prosecutions, and his Track Three expert report is based on his extensive professional experience. Mr. Rafalski is qualified to opine on the effectiveness of Defendants' SOM systems and the consequences of those systems' effectiveness, or lack thereof.

Based on his professional experience and his review of documents and testimony in this action, Mr. Rafalski intends to offer opinions on Defendants' SOM systems and conduct and on the key components that comprise effective controls against diversion. In Mr. Rafalski's opinion, Defendants' SOM systems lacked key components and were not effective controls against diversion. This portion of Mr. Rafalski's opinion is based on Defendants' own descriptions and documentation of their SOM systems. In addition to opining that Defendants' systems, as described by them, were inadequate, Mr. Rafalski also identified seven suspicious-order algorithms. One of these is the methodology set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) ("*Masters*"); Mr. Rafalski offers the opinion that this methodology provides a reasonable estimate and first step to identifying suspicious orders. The other methodologies were used by other registrants, including, for some of

the methodologies, one or more of the Defendants in this MDL. Mr. Rafalski does not opine that any of these other methodologies are an adequate basis for a SOM program; rather, he simply notes that these have been used by opioid distributors in the past and they provide a basis for comparison with the method identified in *Masters*.

III. LEGAL STANDARDS REGARDING *DAUBERT* MOTIONS

A. *Daubert* and Fed. R. Evid. 702

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court provides an analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, pursuant to Rule 702, the district court functions as a gatekeeper, ensuring that the expert is qualified, and his or her testimony is both relevant and the product of reliable methods. *Daubert*, 509 U.S. at 589, 590-91, 592-93; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999).

In *Daubert*, the Supreme Court provided a list of four non-exhaustive factors that a court may use in making its gatekeeping determination of reliability: (1) “whether a theory or technique ... can be (and has been) tested,” (2) “whether the theory or technique has been subjected to peer review and publication,” (3) whether, “in the case of a particular scientific technique,” there is a high “known or potential rate of error” and there are “standards controlling the technique’s operation,” and (4) whether the theory or technique enjoys “general acceptance” within a “relevant

scientific community.” 509 U.S. at 593-94. However, the *Daubert* factors are not definitive or exhaustive. *Kumho Tire*, 526 U.S. at 141, 150 (“*Daubert*’s list of specific factors neither necessarily nor exclusively applies to all experts or in every case” and “*Daubert* makes clear that the factors it mentions do not constitute a ‘definitive checklist or test.’”); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 682 (6th Cir. 2010) (“Our Court has recognized that the *Daubert* factors are not dispositive in every case and should be applied only where they are reasonable measures of the reliability of expert testimony.”). Instead, the test of admissibility under Rule 702 is a flexible one that must be tailored to the facts of each case. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (“The test of reliability is ‘flexible,’ and the *Daubert* factors . . . may be tailored to the facts of a particular case.”); *Tamraz*, 620 F.3d at 682 (the gatekeeping inquiry must be tied to the facts of a particular case, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.”); *accord Kipps v. Caillier*, 197 F.3d 765, 769 n.6 (5th Cir. 1999).

The proponent of the testimony need only show by a preponderance of the evidence that the opinions are admissible. *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001); *Ullman v. Auto-Owners Mut. Ins. Co.*, 502 F. Supp. 2d 737, 742 (S.D. Ohio 2007), *citing In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). And a district court’s determination of admissibility of expert evidence under *Daubert* is reviewed for abuse of discretion. *U.S. v. Kalymon*, 541 F.3d 624, 636 (6th Cir. 2008); *Brainard v. Am. Skandia Life Assur. Corp.*, 432 F.3d 655, 663 (6th Cir. 2005). District courts also have broad discretion in choosing the method to employ in determining the admissibility of expert testimony; a district court need not hold a *Daubert* hearing if the reliability inquiry can be resolved on paper through the submissions of the parties. *See, e.g., Kumho Tire*, 526 U.S. at 152-53; *Scrap Metal Antitrust*

Litig., 527 F.3d at 532. The court’s discretion “is at its zenith during a bench trial.” *Kalymon*, 541 F.3d at 636.

B. The *Daubert* Inquiry Is Not Intended to Replace the Adversary System

“[T]he trial court’s role as gatekeeper [under *Daubert*] is not intended to serve as a replacement for the adversary system.” *Burgett v. Troy-Bilt LLC*, 579 F. App’x 372, 376 (6th Cir. 2014), *citing* Fed. R. Evid. 702 advisory comm. Note (2000); *see also U.S. v. 14.38 Acres of Land, More or Less Situated in Leflore County*, 80 F.3d 1074, 1078 (5th Cir. 1996). *Daubert* makes clear that the appropriate means of attacking admissible, albeit shaky, evidence is through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof. 509 U.S. at 596; *see also United States v. Lang*, 717 F. App’x 523, 534 (6th Cir. 2017) (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. Thus, as in all cases, a jury is free to disbelieve expert testimony that it finds to be flawed.”); *Best v. Lowe’s Home Centers, Inc.*, 563 F.3d 171, 180 (6th Cir. 2009). For example, though an expert’s proponent must establish that the proffered expert is qualified to testify by virtue of his or her knowledge, skill, experience, training or education, a lack of specialization should generally go to the weight of the evidence, not its admissibility. *See First Tennessee Bank Nat. Ass’n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (lack of familiarity with some aspects of the subject matter “merely affected the weight and credibility of his testimony, not its admissibility”); *Laski v. Bellwood*, 132 F.3d 33 (6th Cir. 1997) (district court abused discretion excluding testimony of causation experts who were “only” medical specialists and not experts in biomechanics or accident reconstruction because “[r]equiring such specialization thwarts the goals and purposes of the Federal Rules”).

Daubert and Rule 702 are not intended to provide an automatic challenge to the testimony of every expert. *See Kumho Tire*, 526 U.S. at 150-51. Rather, “the rejection of expert testimony [under *Daubert*] is the exception rather than the rule.” *U.S. ex rel. Tennessee Valley Auth. v. 1.72 Acres of Land In Tennessee*, 821 F.3d 742, 749 (6th Cir. 2016); *Scrap Metal Antitrust Litig.*, 527 F.3d at 530, *quoting* Fed. R. Evid. 702 advisory committee note (2000). Thus, “any doubts [about the admissibility of expert testimony] should be resolved in favor of admissibility.” *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 709 (S.D. Ohio 2016), *citing Daubert*, 509 U.S. at 594; *see also Masters v. City of Indep., Missouri*, 998 F.3d 827, 838 (8th Cir. 2021) (“[T]he cases are legion that ... call for the liberal admission of expert testimony, and [c]ourts should resolve doubts regarding the usefulness of an expert’s testimony in favor of admissibility[.]”) (citations and internal quotation marks omitted).

C. The *Daubert* Inquiry Is Focused on the Expert’s Methodology, Not on His or Her Conclusions

The Supreme Court in *Daubert* was careful to emphasize that the expert’s methodology, not her conclusion, is the subject of the Rule 702 inquiry. Noting that the “overarching subject” of the Rule 702 inquiry “is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission,” 509 U.S. at 594-95, the Court went on to hold that “[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.” *Id.* at 595. The Sixth Circuit has repeatedly echoed this caution. *See, e.g., Superior Prod. P’ship v. Gordon Auto Body Parts Co.*, 784 F.3d 311, 323 (6th Cir. 2015); *Decker v. GE Healthcare Inc.*, 770 F.3d 378, 391 (6th Cir. 2014); *Best*, 563 F.3d at 177; *U.S. v. Demjanjuk*, 367 F.3d 623 (6th Cir. 2004) (where methodology was neither original nor controversial, district court properly admitted expert testimony).

Thus, the role of the district court is to evaluate whether the methodology used by the expert is reliable, *i.e.*, whether, when correctly employed, that methodology leads to testimony helpful to the trier in fact. *See Daubert*, 509 U.S. at 595. Nothing in Rule 702 or *Daubert* and its progeny, or in the rulings of the Sixth Circuit permits this Court to subject an expert's conclusions, as opposed to his methodology, to the *Daubert* analysis. The proponent of expert testimony does not need to prove that the expert's testimony is correct. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531 (6th Cir. 2008) (whether expert's opinion is accurate goes to weight of the evidence, not to its admissibility, and "the district court appropriately passed the torch to the jury to make this determination"); *United States v. Bonds*, 12 F.3d 540, 561 (6th Cir. 1993) ("Disputes about specific techniques used or the accuracy of the results generated go to the weight, not the admissibility of the scientific evidence.").

Moreover, "[a]dmissibility under Rule 702 does not require perfect methodology. Rather, the expert must employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Best*, 563 F.3d at 181. Indeed, in *Best*, the Sixth Circuit held that where the expert's overall methodology was sound, "[a]ny weaknesses in his methodology will affect the weight that his opinion is given at trial, but not its threshold admissibility." 563 F.3d at 182; *see also United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir. 1993) ("[A]ny weaknesses in the factual basis of an expert witness' opinion, including unfamiliarity with standards, bear on the weight of the evidence rather than on its admissibility."); *Paoli R.R. Yard.*, 35 F.3d at 744 ("The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion,

and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.”).

D. Statistical Analysis Is an Appropriate Form of Expert Opinion

In assessing “fit,” *i.e.*, whether an expert’s testimony will “help the trier of fact to understand the evidence or to determine a fact in issue,” Fed. R. Evid. 702(a), the Court must determine whether there is some “connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify.” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000). An expert’s statistical analysis of aggregate rather than solely party-specific evidence does not undermine its relevance or fit. *See, e.g., Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016) (“A representative or statistical sample, like all evidence, is a means to establish or defend against liability. Its permissibility turns . . . on the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.”); *In re Neurontin Mktg., Sales Practs., and Prods. Liab. Litig.*, 712 F.3d 21, 42-43 (1st Cir. 2013) (“[C]ourts have long permitted parties to use statistical data to establish causal relationships.”).

IV. ARGUMENT

A. Rafalski’s Opinions in Track Three are Consistent with the Court’s Holdings from Track One

Moving Defendants incorporate by reference the arguments presented by Track One Defendants in their motion to exclude Mr. Rafalski’s opinions. Doc. #1900. In Track One, this Court partially granted Defendants’ motion, precluding Mr. Rafalski from offering four opinions it found to be impermissible legal conclusions: (a) that the law required distributors to halt all shipments after identifying an initial suspicious order; (b) that DEA regulations require certain key components regarding SOM and due diligence systems; (c) that the CSA requires manufacturers

to consider “chargeback” data; and (d) that the law requires DEA registrants to document and permanently retain records of their due diligence. *See* Doc. #2494 at 21. The Court specifically *permitted* Mr. Rafalski to opine, based on his experience, whether Defendants provided effective controls against diversion. The Court also permitted him to offer the opinion that once an order is flagged as suspicious, all subsequent orders from the same customer remain suspicious unless, as a result of due diligence, the suspicion concerning the first order has been dispelled. The Court similarly allowed Mr. Rafalski to opine what the absence of due diligence records means to him. *See id.* at 12-14.

Consistent with this, Mr. Rafalski’s Track Three expert report describes in detail what, in Mr. Rafalski’s opinion, the key components of a system to maintain effective controls against diversion would be, including procedures to follow for establishing new customers, evaluating orders, conducting due diligence on identified orders, and approving threshold quantities. *See* Doc. #3852, Attachment 13, Expert Report of James E. Rafalski (“Rafalski Report”) at 40-45. He also offers opinions that the Moving Defendants’ SOM systems were inadequate to maintain effective control against diversion. All of his opinions are consistent with, and permitted by, the Court’s ruling from Track One. Moving Defendants contend that review of the summary of Mr. Rafalski’s opinions, found at pages 8-9 of his Track Three report, demonstrates that Mr. Rafalski has fallen afoul of this Court’s Track One order, but the opposite is true. The summary of Mr. Rafalski’s opinions shows that Mr. Rafalski has not offered, in Track Three, the kind of legal conclusions this Court found impermissible in Track One. Mr. Rafalski’s opinions about what, in his experience as a DEA Investigator, constitutes “effective controls against diversion” and whether the systems the Moving Defendants put in place could provide such effective controls are precisely what this Court has already held Mr. Rafalski is permitted to offer.

B. Rafalski's Opinions Regarding Moving Defendants' SOM Systems in Track Three Are Reliable

Moving Defendants acknowledge that the Court's Track One ruling permits Mr. Rafalski to express opinions as to the characteristics of a SOM system and due diligence procedures effective in preventing diversion. Defs' Memo at 9. Nonetheless, Moving Defendants argue that "[n]ew evidence obtained in CT3 discovery"—namely, past DEA inspection reports—should change that ruling and preclude Mr. Rafalski from offering opinions on Moving Defendants' SOM systems. *Id.* The Court should reject this argument. Although Moving Defendants are free to present this "new evidence" to the jury, it does nothing to change Mr. Rafalski's qualifications or the reliability of his methodology. Moving Defendants' arguments regarding their past inspection reports go squarely to the weight of Mr. Rafalski's opinions rather than their admissibility.

1. Under controlling law, Mr. Rafalski may base his opinions on his professional experience without replicating a DEA investigation.

Citing to the Supreme Court's opinion in *Kumho Tire Co.* that experts must "'employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,'" Moving Defendants argue that Mr. Rafalski's opinion should be excluded because he "did not use the same established and reliable methodologies and tools to investigate Moving Defendants that he used as a DEA Diversion Investigator." Defs' Memo at 10 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Moving Defendants complain, for example, that Mr. Rafalski did not "do the type of physical investigation of Moving Defendants' pharmacies that he recommended to identify possible diversion." *Id.* Relying on *Kumho Tire* and the Sixth Circuit's decision in *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426 (6th Cir. 2007), Moving Defendants argue that the fact that Mr. Rafalski did not perform the same type of investigation renders his opinions on Moving Defendants' SOM systems unreliable. *Id.* at 10-11.

Nothing in *Kumho Tire* or *Johnson*, however, classifies Mr. Rafalski's opinions as unreliable if he did not follow the exact steps he would have taken as a DEA Diversion Investigator. The Sixth Circuit in *Johnson* reiterated that a court's gatekeeping role with respect to experts is a "very flexible inquiry," which "'must be tied to the facts of a particular case,' depending on 'the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" *Johnson*, 484 F.3d at 430 (quoting *Kumho Tire*, 526 U.S. at 150). This flexible inquiry is equally applicable to Mr. Rafalski's opinion based on his professional experience as it is to opinions from traditional scientific experts. As the Sixth Circuit explained, "[t]he whole point of *Kumho*, after all, was that the distinction between 'scientific knowledge' (at issue in *Daubert*) and 'technical or other specialized knowledge' (at issue in *Kumho*, as here) is fuzzy at best." *Id.* at 429 (quoting *Kumho Tire*, 526 U.S. at 148). The gatekeeping standards set forth in *Daubert* and *Kumho Tire* do not require Mr. Rafalski to replicate the physical store investigation he would have carried out as a Diversion Investigator.

As Mr. Rafalski has repeatedly testified, his expert opinions are tied closely to his years of experience as a DEA Diversion Investigator.¹ In his expert report, Mr. Rafalski identified various components of an effective anti-diversion program based on his extensive experience evaluating SOM programs, and he assessed Defendants' conduct against these standards. Based on his review of Defendants' documents and testimony, Mr. Rafalski evaluated their SOM systems as a whole. Under *Kumho Tire* and *Johnson*, he may rely on the specialized knowledge developed over years as a DEA Investigator without repeating the steps of a DEA investigation. *See also Wood v. Wal-Mart Stores E., LP*, 576 F. App'x 470, 472 (6th Cir. 2014) ("Particularly in cases involving non-

¹ See Rafalski Dep. Vol. I, Tr. 83:5-84:1; Doc. #3859, Attachment 25, Rafalski WV Trial Tr. Vol. 18 27:10-30:7, 36:8-16; Doc. #3859, Attachment 23, Rafalski *Frye* Testimony 8/17/2020, 79:13-19, 81:19-83:22, 95:24-96:9, 121:13-17, 125:16-126:11; Doc. #3859, Attachment 24, Rafalski *Frye* Testimony 8/18/20, 129:12-130:23.

scientific experts, ‘the relevant reliability concerns may focus upon personal knowledge or experience.’”) (quoting *First Tenn. Bank Nat’l Ass’n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001)); *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934597, at *4 (N.D. Ohio Aug. 20, 2019) (“[T]he [*Daubert*] factors may be pertinent, while in other cases the relevant reliability concerns may focus upon personal knowledge or experience.”) (quoting *Barreto*, at 335)).

2. Moving Defendants’ arguments against Rafalski’s conclusions go to weight, not admissibility.

Moving Defendants raise several specific arguments against Mr. Rafalski’s conclusions as to their conduct based on the evidence he reviewed. These arguments, however, go to the weight of Mr. Rafalski’s testimony, not its admissibility. As noted above, the focus of the *Daubert* inquiry is solely on principles and methodology, not the expert’s conclusions, and nothing in Rule 702 or *Daubert* and its progeny, or in the rulings of the Sixth Circuit, permits this Court to subject an expert’s conclusions, as opposed to his methodology, to the *Daubert* analysis. Moving Defendants’ attack on Mr. Rafalski’s opinions on the basis that (in their view) his conclusions are wrong, or are contradicted by other evidence, thus simply misses the mark. Moving Defendants are free to counter those opinions with the evidence they believe calls them into question, but such evidence provides no basis to exclude the opinions. *See Daubert*, 509 U.S. at 596 (appropriate means of attacking admissible, albeit shaky, evidence is through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof); *accord United States v. Lang*, 717 F. App’x 523, 534 (6th Cir. 2017).

The evidence on which Moving Defendants rely neither calls Mr. Rafalski’s methodology into question nor, indeed, undermines his conclusions. For example, Moving Defendants point to past inspection reports pertaining to Defendant Giant Eagle, arguing that these reports show that

Giant Eagle was in full compliance with the security regulations. *See* Defs' Memo at 9. A closer look at these reports, however, reveals multiple errors and shortcomings, including incorrect pill counts and a complete lack of a SOM program. *See* Doc. # 3855-8, Exhibit 3 to the Decl. of Brian C. Hill: DEA Reports of Investigation – HBC and GERX. Moreover, as Mr. Rafalski testified, whether or not an issue is discovered or detailed by a diversion investigation, the performance of an investigation does not relieve a distributor of its "responsibilities to comply with the regulations." *See* Doc. #3859, Attachment 27, Rafalski Deposition Vol. I, Tr. 81:15-22.

Moving Defendants also complain that Mr. Rafalski was unable to explain why he found a greater percentage of systems to be noncompliant as an expert than he had found as a DEA Diversion Investigator. *See* Defs' Memo at 6 (citing Tr. 46-47, 85-86). But Mr. Rafalski was never asked to explain this purported discrepancy. He did clarify, however, that the 50% estimate may not be correct (*See* Doc. #3859, Attachment 28, Rafalski Deposition Vol. II, Tr. 444:15-445:10), so the purported discrepancy between his findings as a DEA investigator and his conclusions as an expert may not be accurate, and, more importantly, Moving Defendants are comparing apples to oranges. First, Moving Defendants do not indicate which distributors Mr. Rafalski found to be in compliance, or the time period for those findings. The fact that a distributor not involved in this litigation was found to be in compliance at some point in time says nothing about the overall compliance of the Moving Defendants during the relevant time period.

In addition, Mr. Rafalski testified that, in his experience, there have been issues with registrants that were not identified in prior inspections. Rafalski Dep. Vol. I, Tr. 80:8-81:22. He further explained that he did not place "a high value" on reviewing prior inspections because, in his experience, there are usually clean inspections during the timeframe covered by administrative

actions taken against registrants.² Rafalski Dep. Vol. II, Tr. 455:4-17. Moving Defendants also overstate Mr. Rafalski's supposed "admission" that registrants are entitled to rely on their favorable inspection reports. Defs' Memo at 6. What Mr. Rafalski actually testified was that he was "not in total agreement" and that "it would depend on the circumstances." Rafalski Dep. Vol. I, Tr. 79:14-80:5. He further testified "I don't think you can put your full faith that everything is perfectly correct." Rafalski Dep. Vol. I, Tr. 80:19-22. When pressed further, he concluded: "I'd have to say that a registrant is bound to comply with the regulations, and that's not dependent on whether or not an inspection is conducted, and an issue is not found or discovered or detailed by a diversion investigation, it doesn't relinquish the responsibilities to comply with the regulations." Rafalski Dep. Vol. I, Tr. 81:15-22.

Moving Defendants also skew Mr. Rafalski's acknowledgement that DEA security regulations do not require "perfect compliance." Mr. Rafalski's testimony was that "substantial" in the context of 1301.71(b) meant "in compliance" and that "you couldn't find any obvious faults." Rafalski Dep. Vol. I, Tr. 89:4-13; *see also* Tr. 89:14-90:9. This was not an acknowledgment that the Moving Defendants' systems were in compliance (substantial or otherwise), and Mr. Rafalski's opinion is that they were not.

Ultimately, Moving Defendants' criticisms of Mr. Rafalski's opinions on the adequacy of their SOM systems, including conclusions drawn or not drawn from past inspection reports, go to the weight of the evidence, not admissibility. As this Court previously observed, "challenges to the accuracy of an expert's conclusions or factual basis generally bear on the weight of the

² Moving Defendants also point out that Mr. Rafalski did not review the testimony of Ohio Board of Pharmacy agents who inspected Moving Defendants' facilities and found them to be in compliance. Defs' Memo at 6 n.2. Mr. Rafalski testified that the types of inspections conducted by boards of pharmacies are more at a pharmacy level and therefore do not typically address issues similar to those that Mr. Rafalski addresses. Rafalski Dep. Vol. I, Tr. 158:13-159:9.

evidence, rather than its admissibility.” *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934490, at *6 (N.D. Ohio Aug. 20, 2019) (citation omitted). Moving Defendants are free to produce the “new evidence” from Track Three that they believe counters Mr. Rafalski’s opinions, as well as their own experts’ opinions on this evidence, and the jury will be free to decide for themselves how much weight to the evidence presented.

C. Mr. Rafalski’s Opinions as to the Methodologies Used for Flagging Orders and Causation Are Reliable

Moving Defendants contend that Mr. Rafalski’s causation opinions are unreliable because: (a) the opinions are based on unreliable methodologies for identifying potential suspicious orders; (b) Defendants self-distributed opioid products to their own pharmacies; and (c) Mr. Rafalski failed to evaluate “confounding factors” and hence cannot precisely quantify the degree to which Defendants contributed to the harms in Lake and Trumbull Counties. Defs’ Memo at 7-8, 13-14. As explained below, none of these arguments provide a basis to exclude Mr. Rafalski’s causation opinions.

As an initial matter, Defendants mischaracterize the seven suspicious-order methodologies and misunderstand Mr. Rafalski’s testimony regarding these methodologies and the role they play in his analysis. First, these are methodologies that have either been accepted by a federal appeals court as a reliable basis for identifying suspicious orders, *see Masters*, or have been used by other registrants, including other defendants in this MDL. The purpose of identifying these methodologies was to illustrate the various systems that could and have been employed to monitor suspicious orders. *See* Doc. #3859, Attachment 25, Rafalski WV Trial Testimony Vol. 18, 222:1-4 (explaining that he did not disagree with Dr. McCann’s characterization of the methodologies as illustrations). The *Daubert* challenge to the use of methodologies, including several of the methodologies used here, has already been rejected by this Court.

Nor are Moving Defendants correct that because the different methodologies returned a broad range of suspicious orders depending on the Defendant and the methodology applied, the methodologies are inherently unreliable. Defs’ Memo at 13. Indeed, this argument makes no sense. If the various methods that registrants used return vastly different results, that is a reflection of the inconsistency of the approaches among the registrants, not of any flaw in Mr. Rafalski’s methodology. What Defendants call an “astronomical error rate” is not an error rate at all; it is simply different methodologies *that were actually used by registrants* yielding different results. *See* Rafalski Dep. Vol. I, Tr. 115:22-116:10. This is especially true because *Mr. Rafalski does not opine that any of the methodologies other than Methodology A—the one discussed in the Masters case—is an appropriate means of identifying suspicious orders.* To the degree Moving Defendants are demanding that Mr. Rafalski select the appropriate methodology for evaluating their suspicious orders, Mr. Rafalski offers the opinion that applying Methodology A “provides a reasonable estimate and an initial trigger and first step for identifying orders of unusual size.” Rafalski Report at 56-57. That other methodologies, which he does not endorse, but which he is aware have been used, would return very different results does not call into question either his opinion about Methodology A or his use of the other six methodologies as illustrations of what has actually been done in the past.

Similarly, to the extent that Moving Defendants complain about follow-on flagging—Mr. Rafalski’s view that, once an order is flagged as “suspicious,” all subsequent orders of the same drug family from the same customer should be held unless or until the suspicion is cleared through due diligence—this Court also previously held in Track One that this argument goes to the weight, not the admissibility, of Mr. Rafalski’s opinion. *In re Nat’l Prescr. Opiate Litig.*, 2019 WL 3934490 at *6 (“Defendants may argue to the jury that Rafalski’s method is over-inclusive and

only the first order flagged as suspicious required due diligence, not every order placed thereafter.”).

Moving Defendants also argue that because they are self-distributors, they cannot have caused any harm to Plaintiffs unless diversion occurred at their pharmacies, and Mr. Rafalski did not analyze pharmacy level diversion. Defs’ Memo at 7. This argument goes to the sufficiency of Mr. Rafalski’s testimony to provide causation, not to its reliability or its admissibility. Moreover, this Court has already rejected this same argument in Track One. There, too, the Distributor Defendants argued that Plaintiffs had failed to show that diversion actually occurred at any of the pharmacies to which they shipped opioids. But, in denying the Distributor and Pharmacy Defendants motions for summary judgment on causation, the Court explained that:

[G]iven the massive increases in the supply of prescription opioids into the Track 1 Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer these failures were a substantial contributing factor in producing the alleged harm suffered by Plaintiffs. Because Plaintiffs have presented evidence that shows they have suffered the sort of injury that would have been an expected consequence of the alleged wrongful conduct, Plaintiffs have done enough to withstand summary judgement on this issue.”

Doc. #2561, Opinion and Order Regarding Defendants’ Summary Judgment Motions on Causation (“Causation Order”) (Sept. 3, 2019). That Moving Defendants self-distributed opioids does not change the analysis. The corporate relationship between the distribution arms and the individual stores to which opioids were shipped did not relieve the Moving Defendants of their obligation, as distributors, to know their customers. Moving Defendants had the same obligation to ensure that orders it shipped to each of the individual stores in the pharmacy chain were not being diverted; that the stores had the Moving Defendants’ brand name plastered on the front was in no way a substitute for the due diligence every distributor is required to undertake with respect to each of

its customers. Indeed, if anything, the Moving Defendants' obligation was greater, because they had access to more information about the stores to which they shipped than an unrelated distributor would have, including, for example, whether particular stores also received opioid shipments from other distributors. The fact that they self-distributed is an exacerbating, not a mitigating, circumstance with respect to their failure to halt shipments on suspicious orders.³

Defendants also complain that Mr. Rafalski did not evaluate other "possible confounding factors" and did not attempt to quantify the contributions of these other factors. Defs' Memo at 8. But the fact that there may be other potential contributors to a public nuisance does not absolve Defendants of their contributions to the opioid crisis in the Track Three counties. Moreover, at most, this argument goes to the weight of Mr. Rafalski's opinion, not its admissibility. *See* Causation Order at 9 ("[Defendants'] argument overlooks the fact that whether the alleged harm was caused by fraudulent marketing or ineffective controls, or a combination of both, involves questions of disputed facts for the jury to resolve."). Similarly, the fact that Mr. Rafalski does not quantify the contributions of Defendants to the opioid crisis in Lake and Trumbull counties does not invalidate his causation opinion. Defs' Memo at 8. Mr. Rafalski clearly opines, based on his experience as a DEA agent and his review of the evidence, that Defendants substantially

³ Moving Defendants' reliance on *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244 (6th Cir. 2001), is misplaced. *See* Defs' Memo at 12. *Nelson* involved personal injuries allegedly caused by PCB contamination at a natural gas pumping station in Lobelville, Tennessee. In affirming the exclusion of testimony from plaintiffs' medical experts on causation, the *Nelson* court emphasized the lack of "any factual basis from which a jury could infer that the plaintiffs were in fact exposed to PCBs from Station 79," and that "some of the flagship plaintiffs experienced cognitive impairments and mood disorders before ever moving to Lobelville." *Nelson*, 243 F.3d at 253. That is not this case. There is no doubt that the Moving Defendants distributed and dispensed substantial quantities of prescription opioids into the Plaintiff Counties. The red-flag methodology advocated by Mr. Rafalski has been approved by the D.C. Circuit. And this Court has already ruled in the context of Track One that if there is a massive increase in supply accompanied by a failure to maintain effective controls against diversion, one can reasonably infer that such a failure is a substantial contributing factor to the opioid crisis in the Plaintiff Counties. Doc. #2561 at 8.

contributed to the opioid epidemic. The degree of harm caused by Defendants is a question for the jury. *See* Causation Order at 9 n.8 (“[T]he Distributors’ arguments about the extent of harm caused by alleged wrongdoing involves questions of material fact for the jury to decide.”).

Mr. Rafalski testified that there is evidence showing that Moving Defendants’ SOM systems led to actual diversion. *See* Rafalski Dep. Vol. II, Tr. 510:3-17. His testimony here is consistent with his testimony in every case: that he cannot testify which specific pills were actually diverted, but that more likely than not the flagged suspicious orders were diverted.

V. CONCLUSION

For all the reasons set forth, the Court should deny Moving Defendants’ motion to exclude Mr. Rafalski’s expert opinions.

DATED this 18th day of August, 2021.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 18, 2021, the foregoing has been served via email to Defendants' Listserv: xALLDEFENDANTS-MDL2804-service@arnoldporter.com and Special Master Cohen: david@specialmaster.law.

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